REMARKS

Reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are thus respectfully requested.

1. Status of the Claims

Claims 1, 8, 9, 11-15, 21 and 26-30 are pending. Claims 1, 8, 9, 11, 12, 14, 15, 21, 26, 27, and 30 stand rejected. Claims 13, 28, 29 stand objected to, but would be allowable if rewritten in independent form. Claims 2-7, 10, 16-20, and 22-25 stand cancelled.

2. Acknowledgement of Information Disclosure Statement

Applicants note with appreciation the acknowledgement of the Information Disclosure Statement filed May 25, 2007. Applicants request acknowledgement of the Information Disclosure Statement submitted April 19, 2006.

3. Rejections under 35 U.S.C. § 102

Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Sakai et al. (U.S. Pat. No. 5,407,812) [hereinafter "Sakai"]. The Office cited to column 3, line 23 in support of the allegation that Sakai discloses the presently claimed compound. Applicants respectfully traverse the rejection.

A prior art reference does not anticipate a claim unless the prior art discloses, explicitly or inherently, each and every element of the claim. In addition, such disclosure must be "***sufficient*** to have placed a person of ordinary skill in the field of the invention in possession of it." *In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2d 1655, 1657 (Fed. Cir. 1990) (emphasis added). Although Sakai recites "2-O-β-D-glucopyranosyl-L-ascorbic acid" in column 3, line 23, it is certainly a typographical error on the part of Sakai, when Sakai is reviewed as a whole. First, Sakai as a whole is directed to 2-O-α-D-glucopyranosyl-L-ascorbic acid ***only***. Moreover, a reading of relevant paragraphs neighboring the alleged disclosure indicates that what the Office cites should actually be "α-D-glucopyranosyl-L-ascorbic acid." The alleged disclosure states "...to overcome the drawback of ***such an***

amorphous 2-O-β-D-glucopyranosyl-L-ascorbic acid." *See* Sakai, col. 3, lines 22-23 (emphasis added). Nowhere in Sakai dose "2-O-β-D-glucopyranosyl-L-ascorbic acid" appear again. Furthermore, the limitation for the alleged disclosure, i.e. as emphasized in the above quotation, clearly refers to α-form compound, as its amorphous and hygroscopic nature is explicitly described in the prior paragraph. *See* Sakai, col. 3, lines 13-18. Similarly, the two paragraphs immediately after the alleged disclosure refer to α-form compound with improved properties. *See* Sakai, col. 3, lines 27-41. Furthermore, a person of ordinary skill in the field, after reviewing Sakai immediately, would recognize that the alleged disclosure is an obvious typographical mistake and thus would not be in possession of what is presently claimed, i.e. the β–form of the compound.

Applicants direct the Office's attention to the decision in *In re Yale,* 168 U.S.P.Q. 46 (C.C.P.A. 1970). In this case, the Court held that the ordinary chemist would not have been led by the typographical error to use the erroneous compound as an anesthetic even if as a chemist of ordinary skill in the art he would know how to prepare the compound. He simply would not get so far in the thought process as to determine if he knew how to make the compound, as it would have long since been discarded by him as an obvious error. *In re Yale*, 168 U.S.P.Q. at 49. In *Yale*, the Court clearly found that there was no way to assert that a typographical error of a compound could have led the artisan to the compound claimed by the applicants. Here, Applicants assert a similar fact scenario. The skilled artisan would not have been led to use the β-form of the compound. The reference teaches α-forms only and how to make and use α-forms. It does not enable the use β-forms. There is also a clear teaching away from the preparation and use of any β-form. A typographical error listing a compound does not place the public in possession of that compound. *Id.*, at 48.

Accordingly, there is no effective disclosure in Sakai, and hence the Office fails to adduce a *prima facie* case for the anticipation. Applicants respectfully request withdrawal of the rejection and allowance of Claim 1.

4. Rejections Under 35 U.S.C. § 103

Claims 1, 8, 9, 11-12, 14-15, 21 and 26 stand rejected under 35 U.S.C. § 103(a), as well as newly added Claims 27 and 30, as being unpatentable over Sakai et al. as applied above, in view of Kawada et al. (U.S. Pat. No. 4,754,026) ["Kawada"]. Applicants respectfully traverse all 103(a) rejections.

The analytical framework for § 103, originally presented in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), has recently been reaffirmed in *KSR International Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385 (2007). The framework sets out an objective analysis for obviousness/nonobviousness as the following:

1) determining of the scope and content of the prior art;
2) ascertaining the difference between the claimed invention and the prior art; and
3) resolving the level of ordinary skill in the art.

After analyzing relevant prior art, Applicants hereby present the argument by applying the framework to rejected claims in four relevant groups.

Sakai is directed to the 2-O-α-D-glucopyranosyl-L-ascorbic acid compound, its biochemical synthesis through a saccharide-transferring reaction, and its acceptable use in various forms. *See* Sakai, col. 2, lines 60-68, and col. 3, lines 1-6. As stated above, Sakai as a whole is directed to 2-O-α-D-glucopyranosyl-L-ascorbic acid ***only***. Furthermore, as Applicants pointed out previously, Sakai specifically teaches away from any β-form of glucopyranosyl type derivatives of L-ascorbic acid. Applicants bring the Office's attention to column 2, lines 46-49 of Sakai:

> Studies on the β-D-glucopyranosyl type derivatives of L-ascorbic acid confirmed that they hardly exhibit desired physiological activities in living body, especially, in humans.

As admitted by the Office, Sakai does not teach acetylated derivatives recited by Claims 8-9, nor does Sakai teach methods of using the β-derivatives. Office Action, ¶3, page 4. Kawada, on the other hand, only teaches the conversion of uracil derivatives to cytosine derivatives. Specifically, the alleged teaching by Kawada refer to the knowledge that acyl can serve as protecting groups for the hydroxyl groups in sugar molecules. Kawada, col. 2, lines 62-66.

Group I: Claims 1, 14-15, 21, 26, and 30

Claim 1 is directed to the 2-O-β-D-glucopyranosyl-L-ascorbic acid compound. As stated above, Sakai does not teach the presently claimed β-form compound, and it explicitly teaches away from any β-D-glucopyranosyl type derivatives. A person of ordinary skill is unlikely to pursue the synthesis of the β-form compound, because he is merely a person of "ordinary creativity" and "not a automaton." *See KSR*, 82 U.S.P.Q.2d at 1397. In addition,

Applicants observed numerous unexpected and numerous beneficial properties of the claimed β-form compound over the α-form. *See* Specification, Examples 8-12. Noticing such a dramatic discrepancy between the prior art and present invention, a person of ordinary skill in the art would consider the presently claimed β-form compound to be nonobvious.

Claims 14-15, 21, 26, and 30 are directed to various forms of compositions comprising 2-O-β-D-glucopyranosyl-L-ascorbic acid. The Office, relying on *Ex parte Erdmann*, 194 U.S.P.Q. 96 (Bd. Pat. App. & Int. 1975) and *Ex parte Douros*, 163 U.S.P.Q. 667 (Bd. Pat. App. & Int. 1968), rejects the composition claims in the present application. *Erdmann* holds that the new use for old composition does not render composition patentable, while *Douros* holds that addition of a carrier to an unpatentable compound does not render the composition patentable. Once again, Sakai is not directed to the β-form. Thus, the Office improperly applies *Erdmann* and *Douros*, because the β-form is patentable, and compositions with the β-compound have never been disclosed. In addition, Sakai explicitly teaches away the presently claimed β-form compound. A person of ordinary skill in the art would not expect the superior properties of the β-form compound, and hence would not have considered the compositions comprising the β-form compound obvious.

Accordingly, the Office improperly rejects Claims 1, 14-15, 21, 26, and 30 by erroneously insisting that Sakai teaches the claimed β-form compound. The rejection should be withdrawn and the claims allowed.

Group II: Claims 8-9

Claims 8-9 are drawn to 2-O-β-D-glucopyranosyl-L-ascorbic acid intermediates, which have hydroxyl groups of the saccharide moiety protected with acetyl groups. The Office alleges that Kawada and Sakai jointly renders the claimed β-form intermediates obvious, because (1) Sakai discloses the claimed β-form compound, and (2) Kawada teaches that acetyl can serve as protecting groups. Again, Sakai does not disclose the claimed β-form compound. Sakai explicitly teaches away from any β-D-glucopyranosyl type derivatives. Thus, Sakai cannot be combined with any reference. Kawada alone cannot render Claims 8-9 obvious because of its limited teaching. Accordingly, the Office improperly rejects Claims 8-9 under 103(a). The rejection should be withdrawn, and the claims allowed.

Group III: Claims 11-12 and 27

Claims 11-12 and 27 recite methods of the enzymatic synthesis of 2-O-β-D-glucopyranosyl-L-ascorbic acid with a β-glucosyltransferase. The Office erroneously categorizes Claim 27, a dependent claim of Claim 11, to recite compositions comprising the active agent. Office Action, ¶2, page 4. The Office alleges that synthesis of the claimed β-form compound using the β-specific enzyme is obvious under Sakai, because Sakai recites methods to synthesize α-form compound using the corresponding α-specific enzyme. As stated above, Sakai dose not disclose the claimed β-form compound. Sakai explicitly teaches away from any β-D-glucopyranosyl type derivatives. A person of ordinary skill would have been discouraged from pursuing the synthesis of the β-form compound. Furthermore, Applicants again bring the Office's attention to the article of Norio Muto et al., "*Formation of a Stable Ascorbic Acid 2-Glucoside by Specific Transglucosylation with Rice Seed α-Glucosidase*," AGRIC. BIOL. CHEM., 54(7): 1697-1703 (1990) [hereinafter "Muto"]. A summary of Muto is presented in the Specification on page 5, lines 7-17. In Muto, the authors attempted to use a β-specific saccharide-transfer enzyme to obtain β-form derivatives of L-ascorbic acid. The only product, however, seemed to be 6-O-β-D-glucopyranosyl-L-ascorbic acid, which lacks desirable properties. *See* Muto, Table II at 1700. Knowing the undesirable feature of β-D-glucopyranosyl type derivatives disclosed by Sakai and the failure of biochemical synthesis described by Muto, a person of ordinary skill would not have pursued the enzymatic synthesis of a β-form compound with β-specific enzymes. The finding in the presently claimed invention is unexpected. The results are unexpected with either Sakai or Muto, and it would thus be nonobvious to a person of ordinary skill. Accordingly, the Office improperly maintained the § 103(a) rejection of Claims 11-12 and 27.

Overall, the Office's rejections of Claims 1, 8, 9, 11-12, 14-15, 21, 26-27, and 30 are improper. Applicants respectfully request withdrawal of the rejection, and allowance of the claims.

CONCLUSION

In view of the foregoing, Applicants respectfully request the entry of the amendments to place the application in condition for allowance, or in the alternative, in better form for appeal.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is respectfully requested and the fee should also be charged to our Deposit Account. If an Appeal Fee is required to maintain pendency of the present application, the Office is authorized to charge the Appeal Fee and use this paper as a Notice of Appeal.

If any matters remain outstanding, the Examiner is invited to contact the undersigned representative regarding this matter.

Respectfully submitted,

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Mercedes K. Meyer, Ph.D., Esq.
Registration No. 44,939
DRINKER BIDDLE & REATH LLP
1500 K Street, N.W, Suite 1100
Washington, D.C. 20005-1209
Tel: (202) 842-8800
Fax: (202) 842-8465